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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,082	09/24/2001	Wei-Sing Chu	2313-113	1159
6449	7590	09/17/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				SPIEGLER, ALEXANDER H
ART UNIT		PAPER NUMBER		
		1637		

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/869,082	CHU, WEI-SING
	<b>Examiner</b>	<b>Art Unit</b>
	Alexander H. Spiegler	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 June 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 20-26 and 43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 20-26 and 43 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 24, 2004 has been entered.

### ***Status of the Application***

2. Currently, claims 20-26 and 43 are pending and are rejected herein. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made NON-FINAL. Any objections and rejections not reiterated below are hereby withdrawn.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 20, 22-23, 25 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Atwood et al. (USPN 5,364,790).

Regarding Claim 20, Atwood teaches a coverslip for a microscope slide wherein a portion of the coverslip is concave thereby enclosing a known volume when placed onto a microscope slide. *See Figs. 1, 2, 4 and 5; cols. 7-8, 10-12 and 20, for example.*

Regarding Claims 22-23, Atwood teaches the combination of a concave coverslip of Claim 20, a microscope slide and an insert of a control sample sandwiched between a portion of said coverslip and said microscope slide. *See Figs. 1, 2 and 4; cols. 7-8, and 16-17.*

Regarding Claim 25, Atwood teaches a method of performing an assay (e.g., a PCR reaction) on a biological sample on a microscope slide, comprising, a) placing a biological sample on a microscope slide; b) placing the coverslip of Claim 20 on said microscope slide; allowing water, buffer or reagent to flow into the known volume between said microscope slide and said coverslip; and allowing a reaction to occur. *See columns 5-6 and 10-19.*

Regarding Claim 43, Atwood teaches a coverslip for a microscope slide wherein a portion of the coverslip is concave thereby enclosing a constant volume when placed onto a microscope slide. *See Figs. 1, 2, 4 and 5; cols. 7-8, 10-12 and 20, for example. See also col. 8, lines 50-53 (teaching the cover be “impervious” to the diffusion of water vapor); col. 10, lines 18-21 (teaching the formation of a “leak-tight seal”); col. 12, lines 20-23 (teaching the volume is “trapped,” and thus constant); and col. 20, lines 4-7 (teaching the concave cover “defines a predetermined specific volume *for retaining said reagent mixture.*”) (emphasis added)*

### **Applicant’s Arguments**

Applicant argues Atwood “neither teaches, discloses, nor suggest a concave coverslip enclosing a known volume when placed onto a microscope slide.” *See Applicants remarks on page 7.* In addition, Applicant provides a set of three dictionary definitions of the word

Art Unit: 1637

“known,” and argues, “there is a set definition as far as to what constituted how exact or precise the volume must be ‘known’.” *See* Applicants remarks on pages 4-5. Applicant also argues that because the cover of Atwood is compliant, “the volume of the reagent trapped by the cover will not be known, whether or not Atwood describes the concavity as being chosen to define the volume of the reagent or not.” *See* Applicants remarks on page 6. Applicant further argues that “the concavity is doing the defining, and the concavity is variable, since the cover member is compliant, so Atwood has no real idea what that volume will end up being. *See* Applicants remarks on page 6.

### **Response to Applicant’s Arguments**

Applicant’s arguments have been considered, but are not persuasive for the following reasons. First, Atwood teaches the following passages, which demonstrate the volume is “known.”

The degree of concavity is *chosen to define the volume of reagent 13 that will be contained* between the cover 16 and the slide when the seal ring 20 presses the rim portion 19 of the cover 16 against the slide 14. *See* col. 7, line 66 to col. 8, line 1.

A pipet set to deliver the *desired reagent volume* is preferably used, by hand, to deliver the reagent as a droplet close to the center of the concave surface. *See* col. 11, lines 32-34.

Thus, as the rim portion 19 of the cover 16 is compressed to completion, it is preferable for the cover itself to be compliant, so that it can expand to accommodate the *fixed reagent volume* without a large increase in pressure, which otherwise would make assembly difficult. *See* col. 12, lines 23-28.

In our work, we found that the *optimum reagent quantities* for in situ PCR are different than for PCR in solution. *See* col. 16, lines 28-30.

The system according to Claim 3 wherein *said concave position of said cover member defines a predetermined specific volume for retaining said reagent mixture*. *See* col. 20, lines 4-7.

(emphasis added). *See also* above teachings of Atwood.

Next, giving the claims their broadest reasonable interpretation, one of ordinary skill in the art would conclude that Atwood teaches the coverslip enclosing a “known” volume. Specifically, giving the teachings of Atwood (detailed above), one of ordinary skill in the art would have “proved or generally recognized,” “perceived or apprehended clearly and certainly,” and “understood,” Atwood’s coverslip as enclosing a “known” volume. For example, Atwood teaches that the skilled artisan can deliver a “*desired* reagent volume,” the volume enclosed is a “fixed” volume, the degree of concavity is *chosen* to “*define* the volume of reagent,” and that cover member “defines a *predetermined* specific volume” for retaining said reagent mixture. These examples demonstrate one of ordinary skill in the art would conclude that the coverslip encloses a “known” volume because the skilled artisan has control over what volume is going to be fixed, defined or predetermined within the cover. Applicant’s assertion that Atwood has no real idea what the volume will be is unpersuasive and not supported by any evidence. On the contrary, Atwood repeatedly teaches the volume enclosed within the cover is fixed or is a predetermined specific volume (see above).

For these reasons, and those of record, the rejection is maintained.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atwood et al. (USPN 5,364,790) as applied to claims 20, 22-23, 25 and 43 above, and further in view of Pan et al. (WO 97/07241).

The teachings are Atwood are presented above. Specifically, Atwood teaches a concave cover slip, which can be used in a PCR reaction. Atwood does not teach a coverslip comprising reagents dried thereon.

However, drying reagents onto coverslips is well known in the art. For example, Pan teaches a PCR reaction comprising attaching a tissue section onto a coverslip, drying the tissue, and then adding reagents to carry out the PCR reaction. *See* pages 3-10 and example 4. Pan teaches that the tissue can be attached to the coverslip, rinsed in alcohol and allowed to dry prior to PCR. *See* page 5. Pan also teaches that prior to the attachment of the tissue, the coverslip can have a pre-dried adhesive on the surface of the coverslip (page 9), or can simply be dried over night (page 18). Pan teaches the above methods provided a simplified method that is faster, more accurate and less expensive than previous methods of carrying out PCR. *See* pages 1-3.

Accordingly, in view of the teachings of Pan, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Atwood so as to have dried reagents on a coverslip, in order to have achieved the benefit of providing a more efficient, accurate and less expensive method of carrying out PCR.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Atwood et al. (USPN 5,364,790) as applied to claims 20, 22-23, 25 and 43 above, and further in view of Kuan et al. (USPN 6,181,811).

The teachings are Atwood are presented above. Atwood does not teach a coverslip comprising a barcode or text.

However, the use of barcodes or text is a well-known tool for identifying slides or coverslips of interest. For example, Kuan teaches that barcodes can be used for identification purposes in automated systems. *See* Figs. 8a and b and cols. 14-15.

Accordingly, in view of the teachings of Kuan, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the coverslip of Atwood so as to have labeled the coverslip with a barcode or text, in order to have achieved the benefit of providing an effective means for identifying a sample in an automated system.

#### **Applicant's Arguments with respect to the rejections of Atwood in view of Pan or Kuan**

Applicants argue that because Atwood "neither teaches, discloses, nor suggest a concave coverslip enclosing a known volume when placed onto a microscope slide", and neither does Pan nor Kuan, the 103 rejections should be withdrawn. *See* Applicants remarks on page 8.

#### **Response to Applicant's Arguments**

Applicant's arguments have been considered, but are not persuasive for the reasons set forth above in the "Response to Applicant's Arguments" under the 102 rejection of Atwood. Accordingly, because Atwood teaches and discloses a concave coverslip enclosing a known volume when placed onto a microscope slide, Applicants arguments are not persuasive.

#### ***Conclusion***

8. No claims are allowable.

Art Unit: 1637

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

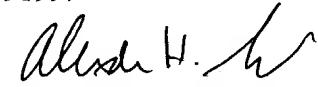
If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (571) 272-0747. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
Alexander H. Spiegler  
September 13, 2004

  
CARLA J. MYERS  
PRIMARY EXAMINER